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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/821,695	Applicant(s) SEVER ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-10-2004</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Golzález.

See section 3.11 of Golzález. The reference is silent on whether the material is crystalline or amorphous. MPEP 2112 states:

“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

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In this case, the “unknown property” is the amorphous form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the amorphous form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253). The “properties” branch of that statement applies here.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's

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burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195

USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Overcoming the rejection is very straightforward. One simply replicates the prior art procedure. If the claimed form does not appear at all in the product, or if on repetition, it sometimes does not appear in the product, then the rejection is overcome.

The reference teaches that the compound is in use as an antibacterial, which is tantamount to a disclosure of the compositions and use.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2004046154 A1.

The reference has two types of products. In example 1, the nature of the material produced is not specified, and thus the situation is the same as in the Golzález situation. In examples 3-4, the product is described as an amorphous monohydrate. The claims here do not state anhydrous or hydrate; they are silent. Thus, the claims are taken to read on both forms. The examiner notes in this regard that the amorphous compound of applicants' is made from the crystalline mono-hydrate, and thus this being a mono hydrate is a very reasonable circumstance. Applicants can overcome this aspect of the rejection by showing that their compound does not contain the monohydrate.

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Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by 6878827, 6350869, and 4559334/4935507.

In 6878827, note publication date of 6/13/2002. See reference example 1-(3). The situation is the same as in Golzález.

In 6350869, see example 3, where the same circumstance arises. Note also example 2, the monohydrate, which thus presents the same issue as in WO 2004046154 A1.

In 4559334, see Examples 14 and 16, material which 4935507 says is "crystalline like amorphous product." That product was used in examples of '307 to prepare a crystalline product. In this regard, the specification states that the material of 4559334 "was not pure and [was] unstable." The claim has no purity limitation, and as noted in the rejection under 35 USC 112, the "stable" limitation is too vague to have any meaning.

In the above rejections, the composition claim 2 reads on any carrier, since none is recited. Such a carrier could be water, and water dissolves physical form. That is, the exact same composition will be obtained regardless of which form is used to prepare the aqueous solution. If claim 1 is amended to put it into form which is allowable over the prior art, this issue can be overcome by putting the word "solid" before "pharmaceutical", which will exclude compositions which are solutions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2004046154 A1, Golzález, 6878827, 6350869, and 4559334/4935507 in view of 6369050 and 6423341.

The primary references are used as above. 6369050 teaches Hydroxypropylcellulose as a standard binder --- see first composition in column 9, thus rendering claims 4 and 7 (but not 8) obvious. In 6423341, see Table 9 which has both L-HPC and PVP, the very ingredients listed in claim 8. These references teach cefdinir generally, so it would be obvious to use any form of the drug with these binders. The examiner also points out that cefdinir is sold commercially as OMNICEF Capsules which contain calcium carboxymethylcellulose, polyoxyl 40 stearate, and gelatin.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 1. The term "stable" is indefinite. How stable? Terms of degree, such as "substantial" or "relatively" are indefinite when the specification contains no "explicit guidelines" to distinguish from things which are not so, *Ex parte Oetiker*, 23 USPQ2d 1651, 1655 (1990) and *Ex parte Oetiker*, 23 USPQ2d 1641, and *Seattle Box Co. v. Industrial Crating & Packaging, Inc.* 221 USPQ 568, 574. Further, stable to what? Heat? Water?**

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- Radiation? Caking? Since there is no way of determining what this term entails, and since all prepared cefdinir products were at least stable enough to characterize, this limitation was not taken into account in determining patentability over the prior art.
2. The phrase "methanolic solution" in claim 10 is unclear. This could mean that a) the solvent is purely methanol, or b) the solvent has at least some methanol present.
 3. Claim 3 fails to recite an actual step. The word "using" does actual do anything", it simply labels what it is that is employed.
 4. The abbreviations in claim 8 must be set forth. Assuming that Hydroxypropylmethylcellulose is intended, it is unclear why this is in the plural, since this is just one things. Is something else intended?
 5. It is unclear whether these compounds are anhydrous or a monohydrate. See the rejection over WO 2004046154 A1.
 6. Claim 2 is improper; composition claim must recite an excipient, or it is just a compound claim.
 7. What does claim 6 refer to? Eudragit NE 30D RL 30D, L 100, RSPO, RLPO. E 100, L100-55, RS 100, S 100 and many others. There is no "Eudragit" per se.
 8. Also, this is a trademark, so it should appear as Eudragit ®.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope.

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The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6, 9-10 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6, 7, 15-16 of copending Application No. 11103183. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 7-8 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 8-13 of copending Application No. 11103183. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is o clear line of demarcation between these overlapping choices. Thus, e.g. claim 8 of 11103183 is just a slightly broader version of claim 7 of 10821695.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
Art Unit 1624

4/11/2006